#23/Reply Brief 3626
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May 23, 04

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re:		
Patent Application of	:	Group Art Unit: 3626
Akers et al.	:	
Appln. No.: 09/851,745	:	Examiner: R. Morgan
	:	
Filed: May 9, 2001	:	
	:	
For: SYSTEM AND METHOD FOR ELECTRONIC MEDICAL FILE MANAGEMENT	:	Attorney Docket No. 015351-0001 (B69465)

Mail Stop Appeal Brief – Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

APPELLANT'S REPLY BRIEF (37 C.F.R. § 1.193)

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TABLE OF CONTENTS

PATENT

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This Reply Brief is being submitted in response to the Examiner's Answer mailed March 9, 2004. As the date for submission of a timely response fell on Sunday May 9, this response is submitted within the two month period of time set for response on Monday, May 10, 2004.

If any additional fees associated with this Reply Brief are due, please charge such fees and credit any overcharge to Deposit Account No. 01-0657. Two additional copies of this Reply Brief are enclosed.

Section (11) of the Examiner's Answer (page 17, last paragraph through page 28) includes new points of argument, mischaracterizes Appellants' arguments, and fails to comply with the requirements of MPEP 1208, which states that the Examiner's Response to Argument must include a "statement of whether the Examiner disagrees with each of the contentions of appellant in the brief with respect to the issues presented and an explanation of the reasons for

the disagreement with any such contention." Appellants' arguments below address only such new points of argument, mischaracterization, and failure to comply with MPEP 1208.

1. Examiner's Mischaracterization of Appellants' Arguments

The Examiner's mischaracterization of Appellants' arguments is most clearly seen by what the Examiner described as Appellants' arguments (A) and (B), which include the statements that the "Examiner fails to disclose" and that the "Examiner fails to teach." Appellants' arguments were directed to individual claims and not to the categories that were arbitrarily constructed by the Examiner, and did not involve anything that the Examiner allegedly failed to disclose or teach. Instead, Appellants argued that the construction of the claims was improper on the grounds that the cited art would not infringe the proper construction of the claims. Appellants do not understand what the basis for the Examiner's position is in stating that the Appellants have argued that the Examiner has failed to disclose or teach anything – the Examiner cannot form a basis for the rejection of the claims under 35 U.S.C. 102 or 103, as an Examiner's statements or arguments do not fall in the class of materials that qualify as prior art under 35 U.S.C. 102 or 103.

In fact, upon review of the Examiner's discussion of Appellants' alleged arguments (A) and (B) on page 21 of the Examiner's Answer, it is apparent that the Examiner is actually discussing what the Appellants allegedly argued that ***Evans*** disclosed, and not what the Examiner disclosed. The Appellants will discuss below the Examiner's characterization of Evans in regards to the rejection of the specific claims that Evans was cited against under 35 U.S.C. 102 or 103, but note that the Examiner has failed to explain whether he disagrees with Appellants' contentions as well having failed to present an explanation of the reasons for the disagreement, as required by MPEP 1208.

2. Patentability of claims 24 through 27

In regards to claim 24, Appellants argued that the claim includes "determining whether a patient file having a predetermined patient data structure exists for a patient on a remote system, transferring the electronic medical data to the patient file if it is determined that it exists, creating the patient file with the predetermined patient data structure on the remote system if it is determined that the patient file does not exist on the remote system; and transferring the

electronic medical data to the newly created patient file on the remote system if it is determined that the patient file does not exist on the remote system," and that the Examiner's construction of these elements to be that disclosed at column 8, lines 21-60 and Figures 1 and 13 of Evans is improper, as Evans would not infringe claim 24 as properly construed. The Examiner's Response to Argument does not state that he disagrees with this contention, nor the contention that claim construction is reviewed *de novo* by the Board of Patent Appeals and Interferences, nor the contention that it needs to be determined *de novo* whether the method disclosed in Evans would infringe the proper construction of claims 24 through 27.

As the rejection of claims 24 through 27 was over Evans, then presumably, the alleged arguments made by Appellants as characterized by the Examiner that are relevant to these claims are (A), (B), (C), (F), (G), and (J). A closer review indicates that the only alleged arguments that are relevant to claims 24 through 28 are (A) and (B), which the Examiner characterizes as follows:

> Evans teaches an electronic medical record system where upon the creation of a patient record, the patient locator (200, Fig. 13) creates a patient data structure (210, Fig. 13) having the PID and the patient's name (see: column 8, lines 29-31). The patient data structure (210, Fig 13) maintains a pointer to an interface files structure (211, Fig. 13) having patient data transmitted from external sources (see: column 8, lines 36-38). In addition, the patient data structure (210, Fig 13) may maintains [sic] a pointer to a legacy file structure (210, Fig. 13) having patient data transmitted from the legacy data system (106, Fig. 1), such as an image of a patient chart (see: column 8, lines 57-60). Furthermore, Evans teaches that the electronic medical record systems transfers patient data from the electronic medical system to other healthcare providers and between external sources (see: column 3, lines 36-42 and column 4, line 64 to column 5, line 8). This plainly shows that a patient record having a patient identification and data structure is created if one does not exist and patient record are [sic] updated before it transferred [sic] to other healthcare providers (see: column 3, lines 36-42 and column 4, line 64 to column 5, line 8).

Focusing on the Examiner's response to alleged arguments (A) and (B), it is evident that Evans does not infringe the proper construction of claims 24 through 27. For example, the Examiner construes a "patient ***file*** having a predetermined patient data structure" as being the patient data structure disclosed at item 210 of Figure 13 of Evans, but he also equates item 210 of Figure 13 of Evans as being a "legacy file structure." Thus, based on discrepancies in the Examiner's characterization of item 210, we must turn to Evans to determine whether item 210 is a "predetermined patient data structure," a "legacy file structure," or something else entirely.

The section of the specification cited by the Examiner (col. 8, lines 29-31) is not helpful. It states "[w]ith reference to FIG. 13, upon creation of a patient record, the patient locator 200 creates a patient data structure 210 having the PID and the patient's name." Thus, patient data structure 210 has the PID and the patient's name, but that it is not the "patient ***record***," nor a "patient ***file***." A further reading of Evans at col. 8, lines 31-60 shows that the patient data structure 210 is merely a collection of ***pointers*** to other patient data structures. It is further shown at col. 8, lines 57-60 that the patient data structure can maintain a pointer to a legacy ***files*** structure 219 having patient data transmitted from the legacy data system 106. Thus, the Examiner has construed a single data file, which can be readily transferred and stored, to be equivalent to an entire database, which, as shown in Evans, can be geographically dispersed and difficult to replicate or transfer.

The Examiner further states that "a patient ***record*** having a patient identification and data structure is created if one does not exist and patient ***record*** are [sic] updated before it transferred [sic] to other healthcare providers (see: column 3, lines 36-42 and column 4, line 64 to column 5, line 8)." However, the cited section of Evans merely states that:

> [s]till another aspect of the present invention includes a method of communicating with an external source having an interface to an electronic medical records system, comprising the steps of finding an interface for the external source, connecting to the external source using the interface, and converting patient data for transfer between the external source and the electronic medical ***records*** system,

and that

> FIG. 1 illustrates the architecture of the EMR system. Healthcare providers, such as physicians, at hospitals, laboratories and clinics, generally capture and access patient data using a point of care system 100 that communicates with a patient data repository 102. Patient data, such as vital signs, x-ray images and laboratory results, resides in the patient data repository 102. The patient data repository 102 also communicates with external sources to obtain patient data, such as laboratory test results and x-ray images, and to transfer patient information, such as prescriptions for medication, from the EMR system to other healthcare providers.

The cited section thus fails to disclose that "a patient ***record*** having a patient identification and data structure is created if one does not exist and patient ***record*** are [sic] updated before it transferred [sic] to other healthcare providers," as argued by the Examiner – instead, it shows that data from "external sources . . . such as laboratory test results and x-ray images," can be

included in the centralized patient record, and that "patient information, such as prescriptions for medication," can be excerpted and transferred "from the EMR system to other healthcare providers."

In contrast, claim 24 includes "creating the patient ***file*** with the predetermined patient data structure ***on the remote system*** if it is determined that the patient ***file*** does not exist on the remote system." Thus, Evans stores the patient record in a centralized location, and ***never creates that patient record on a remote system***." Again, the Examiner's characterization of a single data file as an entire database is incorrect and untenable – Evans would need to create the entire database that is stored at patient data repository 102 at point of care system 100 in order to infringe claim 24.

Appellants further note that the description in Appellants' Brief of the process shown in Figure 2 of Evans is inaccurate – the data record obtained at 111 is never transmitted to the remote location. Instead, it is apparent from the discussion of Figure 13 of Evans at col. 8, lines 29-60, that the remote location only obtains the pointers in the patient data structure 210, and does not even obtain the data record on a temporary basis, as described in the Appellants' Brief. All changes made at the remote location are made to data stored in the patient data repository 102, through the use of pointers to patient data structures 211 through 219. *See, e.g.*, Evans, col. 9, lines 49-60. Thus, the patient record is never transferred to healthcare providers, as asserted by the Examiner, much less a patient file, as provided by claims 24 through 27. Accordingly, the Examiner's construction of claims 24 through 27 as covering the system of Evans is improper and should be reversed.

3. Patentability of claim 28

Claim 28 depends from claim 27 and states that extracting an excerpt of the electronic medical record data from the electronic medical record data file comprises removing user-readable patient identifying data. While Appellants initially indicated that claim 28 stands or falls with claims 24 through 27, based on the Examiner's Answer, it is now believed that Claim 28 does not stand or fall with claims 24 through 27. In particular, the Examiner construes this claim as using "encryption to help protect and preserve the confidentiality of individual patient's medical information," citing to McGauley at col. 6, lines 44-48. However, it is clear that "removing user-readable patient identifying data" is simply not the same as using "encryption to

help protect and preserve the confidentiality of individual patient's medical information," because encrypted user-readable patient identifying information can be decrypted and read, whereas once user-readable patient identifying data has been removed, it cannot be read by any means. The Examiner's construction of claim 28 as covering Evans in view of McGauley is improper, and should be reversed.

4. Patentability of claims 1 through 15, 23 and 29 through 33

Claim 1 includes "a record server having a medical record data file, the medical record data file having medical record data; a record client coupled to the record server, the record client receiving the medical record data file; and wherein the medical record data is encapsulated to prevent modification of the medical record data." In regards to Appellants' argument that the Examiner has construed encapsulation to be synonymous with encryption, and that the Examiner ignores the mandate that "a patentee is free to be his own lexicographer," the Examiner argues that Appellants describe "in ***one particular embodiment***, 'record encapsulation system includes encryption algorithms that generates a value . . . ' This directly shows that encryption is used to encapsulating [sic] a medical record." However, if the Examiner is going to cite to the specification, Appellants would appreciate if he cited it correctly and completely.

The correct and complete citation at page 15, paragraph 36 of the specification reads as follows: "in one ***exemplary embodiment***, record encapsulation system 302 includes encryption algorithms that ***generate a value based on the exact data structure of the entire medical record data file, such that any modifications to the medical record data file can be detected***." By selectively discarding words that do not support his rejection, the Examiner has mischaracterized how Appellants described one exemplary embodiment of a record encapsulation system to support an improper construction of the claims. While encryption algorithms are used in one ***exemplary embodiment*** of a ***record encapsulation system***, they are not used to encrypt, but rather to ***generate a value based on the exact data structure of the entire medical record data file***. That value can then be used by record encapsulation system 302 to determine whether any modifications have been made to the medical record data file, such as by applying the same algorithm to an archive copy of the medical record data file and then by comparing the results to determine whether they are the same. However, it is clear that an encryption algorithm is only one exemplary embodiment of a part of the process of encapsulation – other suitable algorithms

can also be used. Record encapsulation system 302 also performs additional functions as part of the encapsulation of the medical record data file beyond the generation of a value that is based on the exact data structure of the entire medical record data file – it uses that value to detect modifications to the medical record data file, such as by generating the value both before and after the medical record data file has been transferred, so that the two values can be compared to detect whether a change has occurred. The encryption algorithm in the exemplary embodiment of a record encapsulation system described in the specification is clearly not being used simply to encrypt the data, such as for transmission and decryption as shown in Evans, but for a different purpose entirely. As support in the specification for the construction of the term "encapsulating" adopted by the Examiner can only be obtained by discarding portions of the specification that do not conform to that improper construction, it is clear that the Examiner has failed to abide by the Federal Circuit's mandate that "a patentee is free to be his own lexicographer," and must be reversed.

5. Patentability of claims 16 through 19, 34, and 35

Claim 16 includes a "system for distributing medical supplies comprising: a record server receiving package data; a record client coupled to the record server, the record client receiving the package data from the record server and verification data; and wherein the record server receives the verification data from the record client and correlates the verification data to the package data." In response to Appellants' argument that it is improper to construe "receiving package data from the record server with verification data and correlating the verification data to the package data," as the system disclosed by Portwood, the Examiner states that Portwood discloses "a prescription delivery message system that includes a message receiving unit connected to the CPU to receive the prescription delivery message upon delivery of the prescription ***and the matching of prescription data***," citing to column 3, lines 36-41. However, as can readily be seen, the cited section discloses no such "matching of prescription data:"

> In still another preferred embodiment of the invention, the CPU is further programmed to generate a prescription delivery message, and wherein the system further comprises a message receiving unit operatively connected to the CPU to receive the prescription delivery message from the CPU.

It is clear that Portwood fails to disclose verification data, as alleged by the Examiner, and must therefore fail to disclose correlation of verification data to package data. The Examiner's construction of claims 16 through 19, 34 and 35 is therefore improper, and should be reversed.

6. Patentability of claims 20 through 22

While Appellants initially indicated that claims 20 through 22 stand or fall with claims 16 through 19, 34 and 35, based on the Examiner's Answer, it is now believed that claims 20 through 22 do not stand or fall with claims 16 through 19, 34 and 35. In regards to Appellants' argument that it is improper to construe "storing package data corresponding to a sealed package" from claim 20 as the system disclosed by Portwood, the Examiner states in regards to Portwood that "delivery of a patient's prescription implies that the prescription must be sealed before it is delivered to the patient." However, it is common knowledge that packages of prescription drugs received from pharmacists are not usually sealed, and are merely placed in containers with removable tops. The vast majority of pharmacists do not have sealing equipment, such as heat sealing, shrink wrap, or other suitable equipment, and that limitation is simply not disclosed by Portwood, as admitted by the Examiner, and is not even implied. The word "seal" does not occur anywhere in Portwood or Evans. No combination of the systems of Evans and Portwood would infringe the proper construction of claim 20, as they fail to disclose sealing a prescription, and the rejection of claim 20 over Evans and Portwood is therefore improper and must be reversed.

Appellants note that claim 20 was not consistently addressed in each section of Appellant's Brief. This appears to be due to the failure of the Examiner to provide any grounds for the rejection of claim 20 in the Final Office Action dated January 2, 2003. Grounds for the rejection were given in the First Office Action mailed on September 12, 2002, and were assumed to be repeated for the Final Office Action based on the rejection of all claims in that paper.

7. Patentability of claims 2, 11, 23, 31, and 33

In regards to Appellants' argument that it is improper to construe "a sync system verifying that the record client has received a sync file before transferring the medical record data file" of claim 2 as being disclosed in the system of Evans, the Examiner states that the

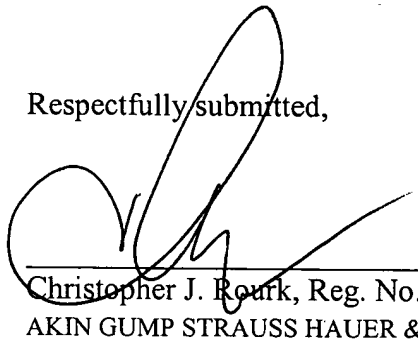
"Examiner considers the sync file to be essentially an updated patient record as the system described in the reference of Evans. This updated patient record involves the steps of comparing and checking to allow an up-to-date medical record to be available to physician [sic]." This argument is both incorrect and non-responsive. Evans nowhere discloses "the steps of comparing and checking to allow an up-to-date medical record to be available to" a physician. The words "compare" and "check" are not even used in Evans. Instead, Evans discloses that the Point of Care System 100 receives the pointers in patient data structure 210, which allow a practitioner at the Point of Care System 100 to access the only version of the up-to-date medical record, as stored in patient data repository 102.

Even assuming that the characterization of Evans was correct, though, comparing and checking one version of a medical record against another version on a remote system would not be the same as "a sync system verifying that the record client has received ***a sync file*** before transferring ***the medical record data file***" – the sync file and the medical record data file are two separate limitations of claim 2. The Examiner's construction of the claim element would read as follows: "a system comparing and matching the medical record data file with the medical record data file to allow an up-to-date medical record to be available to physician." This construction is improper, reads elements out of the claim, does not allow the Appellants to be their own lexicographer, and must be reversed.

AN ORAL HEARING IS NOT REQUESTED

No request for Oral Hearing is being made. However, Appellants note that a Petition for Accelerated Examination under MPEP 708.02(VIII) was granted on January 18, 2002. Since that time, the first Office Action was mailed to an improper address by reason of PTO error, resulting in a delay of approximately eight months, and the Examiner's Answer was not mailed until almost six months after the two month time period specified in MPEP 1208. As such, almost 14 additional months have elapsed beyond the times specified in MPEP, through no fault of Appellants, despite the special status of the application. As such, Appellants respectfully request that this Appeal be advanced out of turn, per MPEP 1204, to avoid any additional delay in resolution of the issues presented herein.

Respectfully submitted,



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